

REMARKS

In an Office Action dated October 29, 2009, the Examiner withdrew the previous rejections of claims 10, 14, 42-49 and 68 as lacking written description, enablement and indefiniteness. Examiner has presently rejected claims 10, 42-44, 47-49, 69 and 70 under a combination of 35 U.S.C. §101 and §112. Applicants respond to each of the Examiner's rejections below. In view of the remarks below, Applicants respectfully request reconsideration of the merits of this application.

STATUS OF THE CLAIMS

Claims 10, 42-44, 47-49, 69 and 70 are under examination. Claims 1-9, 11-41, 45, 46 and 50-68 are cancelled. No new matter has been added to the claims.

REJECTIONS UNDER 35 U.S.C. § 101 AND § 112

Claims 10 and 42-44 are rejected under 35 U.S.C. §101 because the claimed invention is allegedly not supported by either a specific and substantial asserted utility or a well established utility. The Examiner argues that the specification, while asserting a utility for a polypeptide comprising mouse synaptogmin II BoNT/B binding domain and a utility for the ligand (i.e., BoNT/B binding domain for synaptogmin II), "lacks a specific and substantial utility for the claimed complex of a ligand and a polypeptide" (page 3, detailed action).

Similarly, claims 47-49 and 69-70 are rejected under 35 U.S.C. §101 because the claimed invention is allegedly not supported by either a specific and substantial asserted utility or a well established utility. The Examiner argues that the specification, while asserting a utility for a polypeptide comprising mouse synaptogmin II BoNT/B binding domain and a utility for the ligand which is an antibody, "lacks a specific and substantial utility for the claimed complex of a ligand and a polypeptide" (page 5, detailed action).

As a separate yet related issue, claims 10, 42-44 and 69-70 are rejected under 35 U.S.C. §112, first paragraph. The Examiner argues that since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Applicants disagree.

As both rejections rely on the alleged lack of a specific and substantial asserted utility or a well established utility, Applicants have chosen to address the rejections at the same time.

At the outset, Applicants respectfully submit that the lack of utility rejection should be withdrawn. It is well settled law that a lack of utility rejection cannot be rendered "unless it has reason to doubt the objective truth of the statements contained in the written description." *In re Cortright*, 165 F.3d 1353, 1356-1357 (Fed. Cir. 1999). See also *Brana*, 51 F.3d at 1566, 34 U.S.P.Q.2D (BNA) at 1441 ("The PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.") Lack of utility rejections are proper only where an applicant fails to identify any specific and substantial utility for the invention or fails to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966); *In re Fisher*, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005); *In re Ziegler*, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993), or where an assertion of specific and substantial utility for the invention made by an applicant is not credible.

In the present case, Applicants have clearly provided specific and substantial utility as can be taken from the abstract ("...methods of identifying agents that can block the binding between BoNT/B and synaptogmin I or II, methods of identifying agents that can bind to the BoNT/B binding domain of synaptogmin I or II..."), and in greater detail at paragraphs [0045]-[0054]. These passages are specific as they particularly point to the BoNT/B binding domains of synaptogmin I or II and the binding of BoNT/B to those domains in the context of identifying agents that can block interaction between BoNT/B and synaptogmin I or II. Likewise, the utility is substantial as defined in MPEP 2107.01 I.B. ("...Thus a "substantial utility" defines a "real world" use...") as identification of agents that can block binding between BoNT/B and synaptogmin I or II (see paragraph [0044]) has a "real world" use as is also evident from paragraph [0022]. The claimed sequences are clearly within the above scope and utility should not be denied based on lack of specific and substantial utility.

Further, in the context of the discussion in the background at paragraphs [0006]-[0008], one of ordinary skill in the art could not reasonably doubt the utility of the claimed subject

matter. Even without that section, it is well established in the art to use enzyme/ligand complexes to investigate compounds that would interfere with enzyme binding. Clearly, those familiar with the technological field of the invention will immediately recognize the utility. Regarding lack of credibility, it is the burden of the Examiner to establish a reason to doubt in case she chooses to assert lack of credibility, which was not done in the October 29, 2009 Office action.

Regarding the §112 rejection, Applicants assert that a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. *In re Marzocchi*, 58 C.C.P.A. 1069, 439 F.2d 220, 223, 169 U.S.P.Q. (BNA) 367, 369 (CCPA 1971).

In conclusion, Applicants believe the lack of utility rejection and the §112 rejection based thereon over claims 10, 42-44 and 69-70 are not appropriate and reconsideration is respectfully requested.

REJECTIONS OVER CLAIMS 47 AND 49 UNDER 35 U.S.C. § 101 AND § 112

In regards to claims 47 and 49, which recite the limitation "wherein the complex is located *in vivo* in a mammal", the Examiner issues a 35 U.S.C. §101 rejection and asserts that "neither the specification as filed nor any art of record discloses or suggests any specific property or activity for the animals such that a utility would be well established for the animals" (page 6, detailed action). Relating to this, claims 47-49 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner argues that "Applicants broadly claim a transgenic animal", as the claims "read on a complex comprising a polypeptide and a ligand within a transgenic animal" (page 8, detailed action). Applicants respectfully disagree.

Applicants disagree with the Examiner's characterization of claim 47, i.e., that claim 47 reads on the implementation of the transgenic animal *in vivo* assays. Applicants assert that claim 47 recites a complex of antibody with a polypeptide herein the polypeptide is a fragment of synaptotagmin II. In practice, one of skill in the art would not have to use a transgenic animal to QB:960296.99004:9148909.1

produce an antibody or synaptogmin II. Neither does one need a transgenic animal to form the complex claimed in claim 47. Indeed, as demonstrated in paragraphs [00079]-[00081], proteins, such as BoNT/B, can be injected into a mammal and complex can form between BoNT/B and synaptogmin II in the animal. It is well known to one of skill in the art how to inject an antibody into an animal so that the antibody complexes specifically with the protein which the antibody recognizes. Examiner has provided no indication as to why one of skill in the art would not be understand how to do this. Accordingly, Applicants respectfully request reconsideration of the §101 and §112 rejections over claims 47 and 49.

SUMMARY AND FEES

In the present response Applicants present argument against the Examiner's rejections. Reconsideration of the application and allowance are respectfully requested in view of the argument. If all the claims are not allowed, Applicants request a telephone interview with the Examiner and his supervisor. Applicants have enclosed a Petition for Two-Month Extension of Time. No further fees are believed due. However, if further fees are necessary, please charge Deposit Account 17-0055. The Commissioner is also authorized to treat this paper and any future reply in this matter requiring a petition for an extension of time as incorporating a petition for extension of time for the appropriate length of time as provided by 37 CFR § 136(a)(3).

Respectfully submitted,

Date : March 23, 2010

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